IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH *Plaintiffs*, v. MODERNA, INC. and MODERNATX, INC., *Defendants*.	C.A. No. 22-252-JDW
MODERNA, INC. and MODERNATX, INC., *Counterclaim-Plaintiffs*, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH, *Counterclaim- Defendants.*	**JURY TRIAL DEMANDED** **OUTSIDE COUNSEL'S EYES ONLY** **FILED UNDER SEAL**

PLAINTIFFS' SUR-REPLY IN SUPPORT OF
PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT

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TABLE OF ABBREVIATIONS

Abbreviation	Full Description
R.	Moderna's September 5, 2025 Reply in Support of Summary Judgment (D.I. 597)
CM	Plaintiffs' August 22, 2025 Responsive Brief in Opposition to Moderna's Summary Judgment and In Support of Plaintiff's Cross-Motion for Summary Judgment (D.I. 564)
OB	Plaintiffs' July 25, 2025 Opening Brief In Support of Motion for Summary Judgment (D.I. 519)
Pl. R.	Plaintiffs' September 5, 2025 Reply Brief In Support of Motion for Summary Judgment (D.I. 591)
PSOF	Plaintiffs' September 19, 2025 Affirmative Statement of Uncontested Facts, including Moderna's Responses and Plaintiffs' Reply
MSOF	Moderna's September 5, 2025 Statement of Uncontested Facts, including Plaintiffs' Responses and Moderna's Reply (D.I. 599)
M.Ex.	Exhibit to the July 25, 2025 Declaration (M.Exs. 1-81), and September 5, 2025 Declaration (M.Exs. 82-119) of Mark McLennan
M2.Ex.	Exhibit to the August 22, 2025 Declaration of Mark McLennan
Ex	Exhibits to the July 25, 2025 Declaration (Exs 1-29), August 22, 2025 Declaration (Exs 30-99), September 5, Declaration 2025 (Exs 100-121), and September 19, 2025 Declaration (Exs 121-140) of Matthew W. Lachman
M.MTE	Moderna's July 25, 2025 Opening Brief in Support of Motion to Exclude Brill and Pitts (D.I. 511)
MTE	Plaintiffs' August 22, 2025 Response to Moderna's Motion to Exclude and Opening Brief in Support of Motion to Exclude (D.I. 561)
M.MTE R.	Moderna's September 5, 2025 Reply in Support of Motion to Exclude (D.I. 596).
MTE R.	Plaintiffs' September 19, 2025 Reply to Moderna's Motion to Exclude

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CASES

[1] Unless noted, all emphasis is added, and internal citations and quotations are omitted.

OTHER AUTHORITIES

I. The Court Should Enter Summary Judgment For Plaintiffs On § 1498.

A. Moderna's affirmative defense fails the test set forth in the text of § 1498.

Moderna again evades the text of § 1498, this time featuring a new argument that a separate statute, 31 U.S.C. § 6303, dictates that any procurement contract is per se for the Government's benefit. R. 2. That provision's full text, which Moderna brazenly omits, establishes just the opposite: it allows procurement contracts if the contract (1) acquires things for the direct benefit of the Government "***or (2) the agency decides in a specific instance that the use of a procurement contract is appropriate.***" This broad discretion underscores that simply being in a procurement contract does not indicate use or manufacture "for the … Government," as Moderna asserts.

As for the text of § 1498, Moderna argues that Plaintiffs read out the words "or manufactured" by focusing on who the vaccine doses are for. R. 2. That misapprehends the statute and Plaintiffs' argument. Plaintiffs agree that § 1498 covers both use and manufacture—but in both cases, the infringing act still must be ***for the Government***, so its application does not and cannot extend to items the Government requests to be manufactured ***for others***. Congress added "or manufactured" to the statute after the Supreme Court held in 1918 that § 1498 could "not shield [a] contractor from infringement." *Zoltek Corp. v. United States*, 672 F.3d 1309, 1315-16 (Fed. Cir. 2012). But Congress still required that the manufacture—by the Government or a contractor—be "***by or for*** the United States," *id.*, which is where Moderna's argument falters.

Moderna's interpretation would leave application of § 1498 solely to the executive branch—asking only whether the Government included an authorization-and-consent clause. That ignores the statute's two-pronged structure, which makes the Government's consent necessary but not sufficient. Congress decided against leaving § 1498 entirely to the executive branch—adding "for the Government" as an independent check. D.I. 64 at 3. Removing this check would drastically expand § 1498 in a manner Congress never intended, as discussed by Plaintiffs (CM 9-

11) and amici. And assessing compliance does not require a fact-intensive evaluation. Indeed, there is no fact dispute here on the "for the Government" prong, as Moderna does not contest the distribution data showing over 98% of doses going to the public, not the Government. PSOF ¶ 7.

In an effort to nullify the "for the Government" requirement, Moderna claims (without citation) that whether infringement is "for the benefit of the Government" only "expands" the Government's liability. R. 4. Not so. "Benefit" to the Government is how courts uniformly interpret the "for the Government" prong. *Sevenson Env't Servs., Inc. v. Shaw Env't, Inc.*, 477 F.3d 1361, 1365 (Fed. Cir. 2007); *IRIS Corp. v. Japan Air.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014). And adding another prerequisite to liability, by definition, can only constrain—not expand—the scope of that liability. Not only is Moderna's argument wrong, it directly violates the axiom that a statute's waiver of sovereign immunity must be interpreted narrowly. *Zoltek*, 672 F.3d at 1318.

Unsurprisingly, the "for the Government" prong has been applied to preclude the application of § 1498 where, as here, the benefit to the Government is incidental or a byproduct of the infringement. *E.g.*, *Larson v. United States*, 26 Cl. Ct. 365, 369 (1992); *Riles v. Amerada Hess Corp.*, 999 F. Supp. 938, 940 (S.D. Tex. 1998). Moderna does not dispute Plaintiffs' argument that the broadly felt benefits of the vaccine were byproducts of vaccinating the public, rather than a direct benefit to the Government. *See* CM 9. Instead, Moderna seeks to distinguish these cases based solely on the absence of express authorization and consent. But those cases also separately evaluate the "for the Government" prong. *Larson*, 26 Cl. Ct. at 369; *Riles*, 999 F. Supp. at 940. Moderna ignores entirely *Larson*'s analysis on that prong, which, as Judge Goldberg held, cannot be squared with Moderna's statutory (mis)interpretation. D.I. 31 at 12; D.I. 64 at 3. Indeed, Moderna never addresses Judge Goldberg's conclusion—from Moderna's briefs, one would think § 1498 was never previously briefed, let alone the subject of two prior opinions in this matter.

In dismissing this authority, Moderna claims Plaintiffs failed to identify any case involving a procurement contract with express authorization and consent where § 1498 did not apply. R. 4. Not so. Although Moderna attempts to distinguish *Carrier Corp. v. United States*, 534 F.2d 244 (Ct. Cl. 1976), as solely addressing authorization and consent, R. 4, Moderna's own MTE Reply (at 4) acknowledges that *Carrier* held "the contract ***was not 'for the Government'*** because hoisting detachable refuse containers for transport to a dumping site had no 'relation to the function performed by the Government.'" That so few cases address Moderna's § 1498 expansion theory only underscores that it is unprecedented. Judge Goldberg and three retired judges in amici have rejected Moderna's theory unanimously. Tellingly, Moderna *still* cannot cite any case that applies § 1498 to the Government paying a private party to provide goods or services used by the public.

B. Section 1498 cannot shield inducement of private third-party infringement.

Moderna's indirect infringement is a separate harm subject to an entirely separate cause of action. In its marketing and labeling, Moderna—a private party—encouraged other private parties (doctors and pharmacists) to infringe. PSOF ¶ 78. The Government does not touch that separate conduct. Thus, even if the Court agreed with Moderna that its manufacture was "for" the Government (it was not), § 1498 cannot shield Moderna from liability for separately encouraging private actors to infringe. *Decca Ltd. v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980).

Moderna misleadingly suggests the Federal Circuit subsequently overruled *Decca* in *Zoltek*. R. 6. It did not. *Zoltek* expressly clarified that it was *not* addressing "indirect infringement, under § 271(b), (c), and (f), which is not before us." 672 F.3d at 1327. *Zoltek* held only that the terms "used or manufactured" in § 1498 do not incorporate the meaning of those words from the patent infringement statute, 35 U.S.C § 271(a). *Id.* at 1320. The court explained that this holding was consistent with *Decca*, since *Decca* concluded "inducement and contributory infringement are outside § 1498(a) because they 'do not involve *the Government's* making or using a patented

invention.'" *Id.* (quoting *Decca*, 640 F.2d at 1170 & n.31). That also explains why § 1498 applied in Moderna's cited cases, where the Government was liable for the underlying act of direct infringement: the infringement did "involve the Government's making or using a patented invention." *Id.*; *Astornet Techs. Inc. v. BAE Sys., Inc.*, 802 F.3d 1271, 1277 (Fed. Cir. 2015) ("The direct infringement alleged as a prerequisite for the alleged indirect infringement is a use of the patented invention 'by ... the United States.'"); *Morpho Detection, Inc. v. Smiths Detection Inc.*, 2013 WL 5701522, at *6 (E.D. Va. Oct. 17, 2013). But here, the predicate direct infringement (for indirect infringement purposes) was committed by private third parties, not the Government or Moderna. Ex 48 (Mitchell) ¶¶ 764-767. Moderna's encouragement of that private infringement is a separate wrong distinct from its manufacture, for which § 1498 provides no protection.

C. Moderna's fraudulent misrepresentations at least create a dispute of fact.

Histrionic rhetoric aside, Moderna's argument fails to avert a genuine dispute of fact as to authorization and consent based on its misrepresentations to the Government. Moderna claims Plaintiffs did not disclose their fraudulent inducement theory. R. 7. But the interrogatory response Moderna cites (and then ignores) alleges clearly that "Moderna's inducement to the Government to enter into the -0100 Contract, based on misrepresentations, voids any applicability of FAR Clause 52.227-1." M.Ex. 119 (Plaintiffs' Rog 14 Resp.) at 5. Nor did Moderna assert § 1498 as a counterclaim, which would have required Plaintiffs to plead fraud in response (as in *SmartSignal*, D.I. 44, No. 1:02-cv-07682 (N.D. Ill. 2005)). Plaintiffs are "not required to file a response" to "affirmative defenses." *Soler v. Fernandez*, 2015 WL 5771929, at *3 (M.D. Pa. Sept. 29, 2015).

Moderna is also incorrect when it says Plaintiffs "dropped" the '069 patent. R. 7. Plaintiffs maintain the '069 patent is infringed but are not seeking redress at trial to comply with the Court's narrowing Order, D.I. 475. That said, it is untrue that "0%" of the "initial version of Moderna's vaccine infringed." R. 7. Moderna omits that its citation is for literal infringement; its v1 vaccine

infringed the '069 patent under the doctrine of equivalents, Ex 48 (Mitchell ¶¶ 680, 738), showing Moderna's statement to the Government to be false. *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1583 (Fed. Cir. 1996) (DOE can support willful infringement). And crucially, even if it were true that Moderna's representation only addressed one patent explicitly, that does not absolve it of fraudulently omitting that its vaccine infringed other Asserted Patents. *See* 26 Williston on Contracts § 69:2 (4th ed.) ("[A]ffirmative misrepresentation is not required.").

Finally, Moderna simultaneously attempts to use the C-100 contract as a sword and a shield, relying on it for its § 1498 defense while asserting it cannot be challenged by Plaintiffs as a non-party. Although "[n]on-third-party beneficiaries to contracts usually cannot show that they have suffered an injury to a legally protected interest ... when jurisdiction is otherwise proper, there is no inherent bar prohibiting a stranger to a contract from asking the court to interpret a contract that has bearing on its case." *Yellow Pages Photos v. Ziplocal, LP*, 795 F.3d 1255, 1266 (11th Cir. 2015). Thus, parties invoking the "first sale" copyright doctrine can challenge third-party license agreements. *Id.* at 1267. Similarly, tortious interference defendants can challenge the validity of the underlying contract. *Park Lawn v. PlotBox Inc.*, 2021 WL 5038751, at *2 (D. Del. Oct. 29, 2021). Moderna asks the Court to rely on the authorization and consent in the C-100 contract to grant it summary judgment and deny Plaintiffs a jury trial and potential enhanced damages. *Return Mail, Inc. v. USPS*, 587 U.S. 618, 622 (2019). Plaintiffs are entitled to challenge the validity of that contract. *SmartSignal v. Expert Microsys., Inc.*, 2006 WL 1343645, at *2 (N.D. Ill. 2006).

II. The Court Should Enter Summary Judgment For Plaintiffs On Indefiniteness.

A. Lipid Composition Patents

Moderna no longer disputes that the "test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a [POSA] the bounds of the invention." *SmithKline*

Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1340-41 (Fed. Cir. 2005); CM 28. Nor does it identify any ambiguity about the "bounds of the invention," which undisputedly covers a single particle with recited lipids and amounts. CM 28; R. 14-15. And although Moderna insists that Plaintiffs misconstrued Dr. Prud'homme's opinions, R. 16-17, Moderna largely abandons its legally unsound position that the claims are indefinite because the composition "of individual LNPs" is "impossible to measure." CM 27; MTE R. 5-7. Instead, Moderna argues that there are ***too many*** ways to measure infringement, asserting indefiniteness in view of purported differences in Plaintiffs' expert's testing data. R. 14-15. That is legally and factually wrong.

First, measurement differences are legally insufficient to prove indefiniteness. *Presidio Components v. Am. Tech. Ceramics*, 875 F.3d 1369, 1377 (Fed. Cir. 2017) (disputes as to "proper application of the test methodology ... are disputes about whether there is infringement, not" indefiniteness). Judge Bryson recently rejected Moderna's argument squarely: "The problem of inconsistency in test results is entirely different from the problem of indefiniteness" in the *Teva*, *Dow*, and *Saso* cases that Moderna cites. *Kaneka Corp. v. Designs for Health, Inc.*, 2025 WL 1684677, at *5 (D. Del. June 16, 2025). Those cases involved "definitional" disputes, where the claim "meaning[] w[as] tied up with methods of measurements"; that is distinct from cases where, as here, the claims have a "singular meaning." *Id.* Moderna's *Kaneka* case likewise involved a term ("mole %," unrelated to mol% here) that depended on unspecified factors, like how cells were stored, which created a dispute about the "scope of [the] limitation." 2018 WL 2718036, at *9, 14 (C.D. Cal. Apr. 5, 2018). Here, there is no "definitional" dispute (1) that the claims cover a particle with the claimed composition or (2) about the math to calculate lipid mol%. PSOF ¶¶ 17, 85.

Second, even were its argument legally relevant, Moderna has no evidence that any difference in "measurement is in fact outcome-determinative" to infringement. *Takeda Pharm.*

Co. v. Zydus Pharms., 743 F.3d 1359, 1367 n.4 (Fed. Cir. 2014). Despite referencing an "extensive record" of such differences, R. 15, Moderna's brief fails to identify a single outcome-determinative difference. The reason for the omission is plain—while Moderna's expert speculated that different fractionation techniques "*may*" yield "different results," CM 29, the data show otherwise.

Moderna purports to identify two types of "materially different results": (1) differences between fractionated and unfractionated data, and (2) differences between data generated using different parameters for the same type of test. R. 15; PSOF ¶ 92. As to the first type, Moderna cites no expert testimony discussing the data it relies on (PSOF ¶ 92, sample A-1), and its attorney argument is insufficient. *Invitrogen Corp. v. Clontech Lab'ys Inc.*, 429 F.3d 1052, 1068 (Fed. Cir. 2005). Moderna's argument is, in any event, frivolous: testing an unfractionated sample yields one overall value, whereas testing fractions of that sample yields information about the underlying compositional distribution of particles within the sample. Ex 48 (Mitchell) ¶ 612; Ex 128 (Mitchell Reply) ¶ 354. Moderna's argument is akin to comparing the average temperature in a month to the average daily temperature. A monthly average of 47° does not mean the daily temperature never exceeded 50° and does not conflict with a single-day average temperature of 52°. Likewise, Moderna's observation that the measured cationic lipid of one unfractionated sample was 47.278 mol%, PSOF ¶ 92, does not mean the sample lacks particles with > 50 mol%. Indeed, the patent describes the particles' cationic lipid range of "±5 mol %," M.Ex. 97 (Murthy) ¶ 1224; '378 patent, 70:37-38, and fractionation confirmed the sample contained (infringing) particles with 52.022 mol% cationic lipid. PSOF ¶ 92. These values are fully consistent with each other and the patent's teaching. They merely reflect different resolutions of data. *Takeda*, 743 F.3d at 1367 (different results "obtained using various instruments are all equally correct, but each simply may be expressing its correct results in different terms"); PSOF ¶ 83.

As for the second category, Moderna's brief claims to identify supposedly "materially different" *fractionation* data, R. 15, but its PSOF cites (¶ 92) describe results for *non-fractionated* samples (M.Ex. 98 ¶¶ 44-45). Mischaracterization aside, these method development data were from a "defective" testing system and are thus irrelevant to indefiniteness. PSOF ¶ 92; *Janssen Pharm., Inc. v. Teva Pharm. USA, Inc.*, 97 F.4th 915, 937 (Fed. Cir. 2024). Regardless, *all the testing Dr. Prud'homme cited did identify infringing fractions*, PSOF ¶ 92, and thus cannot provide the requisite "outcome-determinative differences." *Takeda*, 743 F.3d at 1366-67. Moderna fails to identify a single instance where one fractionation test showed infringement but another did not.

Moderna also argues that Plaintiffs did not "show a method of measuring" the "in-process" particles Moderna manufactures. R. 16. Moderna's reliance on the alleged difficulty of measuring infringement in its own process clearly violates *SmithKline*. It also overlooks that *Moderna* bears the burden of proof yet cites no evidence—beyond expert speculation—that measurements of the intermediate particles would be difficult or yield variable results. CM 30; PSOF ¶ 35, 87.

Moderna's remaining arguments are equally meritless. It asserts a lack of methodology in the specification, R. 14-15, but "there is no requirement for the specification to identify a particular measurement technique," *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015). Moderna agrees that techniques for lipid composition measurement and fractionation were known and routine. CM 29; Pl. R. 16. Moderna claims that Plaintiffs "cycled through different tests." R. 15. But Dr. Mitchell consistently relied on Moderna's certificates of analysis and the parties' fractionation testing. *E.g.*, Ex 128 (Mitchell Reply) ¶¶ 365-367. While "Moderna's target ratio" (R. 15) makes infringement likely (as its President understood, CM 15), Plaintiffs never suggested that the claims are directed to such inputs. To the contrary, the parties do not dispute what the claims mean, which is why summary judgment for Plaintiffs is proper.

B. The '651 Patent

The parties also do not dispute the scope of the '651 patent under the Court's *Markman* decision. Moderna's citation to the legal standard, R. 17, misses the point—the decision is dispositive not because the Court issued a construction, but because it resolved which mRNA strands count as "fully encapsulated": those "fully contained inside the vesicle." CM 30-31; D.I. 266 at 36. The only ambiguity Moderna identified is a strand "part-in-part-out" of a particle. CM 30-31. Not only is such a strand invented by Moderna's attorneys (both parties' witnesses testified they had never seen it), CM 32; PSOF ¶ 38—if it did exist it would be plainly excluded from the claims by the Court's decision, resolving any ambiguity, CM 31. Plaintiffs challenged Moderna to "identify uncertainty about the scope of the term," by "citing scenarios where it would be unclear if mRNA was 'fully encapsulated.'" CM 31. Moderna did not do so. Instead, it asks the Court to review "Dr. Prud'homme's 30 pages of analysis" on its own to understand the "many problems with the term 'fully encapsulated.'" R. 18. Moderna leaves that exercise to the Court because its expert did not identify any ambiguity in that term. CM 31. That failure of proof is dispositive.

Moderna also contends the claims are indefinite because "Plaintiffs have failed to explain" how a POSA would measure full encapsulation. R. 18-19. That is wrong—Plaintiffs identified techniques that measure full encapsulation (precluding summary judgment for Moderna). CM 34. More to the point, *SmithKline* renders Moderna's critique irrelevant, CM 32; MTE R. 5-7, and Moderna cites no case holding claims indefinite because infringement was difficult to assess.

Moderna asserts that there is ambiguity about what "partial encapsulation" means and how to measure it. R. 18-19. That is irrelevant under *SmithKline*. And measuring partial encapsulation is unnecessary because the claims' numerical limitation *only* recites *full* encapsulation. CM 34. Moderna still does not identify a scenario where the POSA would be unsure whether mRNA is "partially" or "fully" encapsulated, much less evidence such ambiguous mRNA exists. CM 32.

Moderna contends (without expert testimony) that Dr. Mitchell's patent application discusses partial encapsulation and that Plaintiffs identified other types of "partially encapsulated" mRNA ("disordered mixtures" and "surface adhered"). R. 18-19. But Mitchell's patent claims "*at least*" partial encapsulation and describes its LNPs as fully encapsulated. PSOF ¶ 53. "Disordered mixtures" in the '651 patent are distinct from the claimed fully encapsulated systems. MSOF ¶¶ 120, 178-180. And Plaintiffs' witness only stated that "surface absorbed" mRNA "may" exist, and, in any event, could be distinguished from full encapsulation. MSOF ¶ 122. Indeed, Moderna does not contend the POSA would be uncertain about whether *any* of those hypothetical mRNA states are "fully encapsulated." And while Moderna asserts "undisputed evidence" "confirming" "part-in-part-out" mRNA exists, R. 19, its citations do not support this contention and Moderna's witnesses admitted to having no such evidence, PSOF ¶¶ 54-55. Regardless, the Court held that hypothetical "half-in-half-out" mRNA is outside the claim. There is thus no ambiguity.

Finally, Moderna's argument that Blenke reported different encapsulation results, R. 19-20, fails to raise a material dispute because Moderna does not contend that such differences create ambiguity in *claim scope*. *Supra* II.A. By contrast, the different measurements in Moderna's *HZNP* case *did* render ambiguous the "better drying time" claim term. 940 F.3d 680, 698 (Fed. Cir. 2019). Moderna's Reply does not remedy its argument's factual defects. ***First***, Moderna has no evidence that Blenke's methods were reliable or were used to measure *encapsulation* at the priority date, and the citation to Dr. Murthy, R. 20, is inapt, because his testimony was *not* about measuring encapsulation. MSOF ¶ 143; PSOF ¶¶ 60, 64. ***Second***, Blenke did not use mRNA, and it attributed the observed variability to the (unclaimed) type of nucleic acid used. *Id.*; CM 33. ***Third***, Moderna never disputes that Blenke's results were *not* "outcome-determinative" for claim 1. CM 33; MSOF ¶ 144. Each of these facts independently defeats Moderna's irrelevant argument.

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